

REMARKS

Claims 8-54 are pending in this patent application. Of these claims, claims 8, 31 and 43 are independent claims.

In the Office Action of December 13, 2007, claims 8-54 were all rejected as obvious under 35 U.S.C. §103(a) over FLETCHER-HAYNES et al. U.S. Published Application No. 2001/0034614, in view of WITHERS U.S. Patent No. 5,752,234, and in further view of an ARTICLE "Red tape tying up supplies of blood-clotting product", Orange County Register, November 24, 1988.

The present invention is directed to a system (Claims 8-30), a computer readable medium (Claims 31-42) and a method (Claims 43-54) for managing an inventory of blood component collection soft goods to prevent the use of such soft goods which have been quarantined before they are used. Blood component collection soft goods typically come in a sealed package and provide the equipment for the collection of the blood or blood components from the donor, such as tubing, needles, containers and solutions needed for that purpose. See, paragraphs 0392-3. Some of such soft good packages may become quarantined before they are used (paragraphs 0105, 0268 and 0392-3) for any one of a number of possible reasons, such as previously opened or

not sterile, becoming damaged or kinked, having passed the applicable use date or having been superseded by upgraded soft goods.

FLETCHER-HAYNES et al. discloses a computerized blood collection system which is designed to optimize and maximize the yield of desired blood components, such as platelets, plasma and red blood cells. See, the Abstract and paragraphs 0162 and 0195. Disposable tubing such as may be utilized during the blood collection may also be identified and recorded (paragraph 0083), tubing size type and bag identifiers may be recorded (paragraph 0125) presumably to be able to determine which tubing was used with a given donor, and the type of tubing may be placed in the final report (paragraph 0166). However, there is no disclosure or suggestion whatsoever in FLETCHER-HAYNES et al. of inventorying any of the blood component collection soft goods and of quarantining such blood component collection soft goods either before or after use in the collection of blood from the donor. FLETCHER-HAYNES et al. is absolutely silent in those aspects.

Of course, it should be noted that FLETCHER-HAYNES contains 316 paragraphs of specification and 44 pages of drawings. In short, FLETCHER-HAYNES is a very comprehensive disclosure. Thus, if quarantining of unsuitable soft goods,

as defined in independent Claims 8, 31 or 43 herein, was obvious to any of the several inventors of FLETCHER-HAYNES, it is appropriate to conclude that such teachings would have been included in FLETCHER-HAYNES at the time of its filing. Applicants respectfully submit that the fact that FLETCHER-HAYNES is devoid of any such teachings is strong evidence that the presently claimed invention is non-obvious.

In summary, FLETCHER-HAYNES teaches absolutely nothing about:

- Quaranting unsuitable blood component collection soft goods,
- Managing the inventory of unsuitable blood component collection soft goods,
- Providing a database to keep track of the inventory of unsuitable blood component collection soft goods,
- Preventing the use of unsuitable blood component collection soft goods, and/or
- Providing an interface with a quarantine field for indicating that a portion of the blood component collection soft goods is currently in quarantine.

Recognizing that FLETCHER-HAYNES clearly does not disclose or suggest the quarantining of anything, WITHERS is cited for its disclosure of a method and package for supplying health care workers with disposable supplies appropriate for a single patient visit by the health care worker. The disposable supplies which are determined to be needed by the patient during the visit are placed into a disposable container and then delivered to the site where the patient is to receive the treatment prior to the visit by the health care worker. For example, the disposable supplies may be syringes, cotton balls, and the like (Col. 1, lines 18-24).

Once treatment is performed on the patient by the health care worker, any dispensed medical supplies that were in the package and used in the treatment become medical waste which the health care worker puts back into the package. At this time the original package is considered to be a medical waste package. The health care worker permanently seals the waste package and a bar code on the package identifies the package for shipment of the package to a disposal site. In short, WITHERS deals with disposal of suitable medical disposables after the intended use; not with quarantining unsuitable soft goods prior to their use as claimed in the present application.

WITHERS fails to disclose or suggest that the package of disposable supplies which it addresses has anything to do with the collection of a blood component from a donor or that the supplies include a blood component collection soft good, as claimed in the present application. Accordingly, one skilled in the art would not look to WITHERS for a teaching that a blood component collection soft good such as utilized in the system of FLETCHER-HAYNES should be inventoried and quarantined as set forth in each of the independent claims in the present application.

Moreover, each of the independent claims in the present application sets forth that the blood component collection soft good quarantine information is processed prior to the use of the blood component soft good. WITHERS contains no disclosure or suggestion whatsoever that quarantine of any of its packages or disposable medical supplies is processed prior to their use. Indeed, even after use, WITHERS does not maintain any quarantine of the used supplies. Instead, the address is covered up and the remaining supplies are disposed of. See, Abstract of WITHERS. Unlike the present invention, since the supplies after use in WITHERS are quickly disposed of, there is no need to quarantine any of the supplies, nor to maintain a quarantine database on a system computer.

In summary, WITHERS teaches absolutely nothing about:

- A blood component collection procedure,
- Blood component collection soft goods,
- Quaranting unsuitable blood component collection soft goods,
- Managing the inventory of unsuitable blood component collection soft goods,
- Providing a database to keep track of the inventory of unsuitable blood component collection soft goods,
- Preventing the use of unsuitable blood component collection soft goods, and/or
- Providing an interface with a quarantine field for indicating that a portion of the blood component collection soft goods is currently in quarantine.

Accordingly, even when FLETCHER-HAYNES et al. has been modified by the teachings of WITHERS, a system (Claim 8), computer readable medium (Claim 31) or method (Claim 43) is not created including a blood component collection soft good inventory and quarantine information relative thereto, which is processed prior to the use of a blood component

collection soft good.

The ARTICLE does not cure any of the deficiencies of the FLETCHER-HAYNES or WITHERS references, whether considered singly or combination with the other two references. This ARTICLE is concerned with concentrates for treating of hemophilia which may be contaminated with hepatitis or AIDS. Of course, these concentrates are already collected in some type of container (which is not specified or identified). Where the concentrates are already collected in a container, any concerns about whether the container was, or should have been, quarantined are already moot. Moreover, any contamination of the concentrate is also determined after the concentrate is collected. There is absolutely no appreciation, disclosure or concern in this ARTICLE of quarantining any defective containers prior to collection of the concentrate therein. The ARTICLE therefore teaches nothing relevant to the present invention as claimed in independent Claims 8, 31 or 43. In fact, as literally construed, this ARTICLE teaches away from the present invention.

In summary, the ARTICLE teaches absolutely nothing about:

- A blood component collection procedure,
- Blood component collection soft goods,

- Quaranting unsuitable blood component collection soft goods,
- Managing the inventory of unsuitable blood component collection soft goods,
- Providing a database to keep track of the inventory of unsuitable blood component collection soft goods,
- Preventing the use of unsuitable blood component collection soft goods, and/or
- Providing an interface with a quarantine field for indicating the portion of the blood component collection soft goods currently in quarantine.

To the extent that judicial notice has been used to cure any of the shortcomings of the cited references, the Applicants request that evidentiary support for such judicial notice be made part of the record herein so that they may respond to it, or that such judicial notice be withdrawn. Otherwise, the Applicants object to the use of judicial notice. The fact that none of the cited references fairly disclose or teach the quarantine of unsuitable blood component collection soft goods prior to use is evidence that use of judicial notice in this instance is inappropriate. Clearly, any missing claim elements in the

present claims are not notoriously well-known as asserted in the Office Action. Otherwise, if so notoriously well-known, the missing claim elements could be found in the currently cited prior art -- which they are not.

For the above reasons, it is respectfully submitted that all of the claims remaining in the present application, claims 8-54, are in condition for allowance. Accordingly, favorable reconsideration and allowance are requested.

CONCLUSION

A petition for a one-month extension of time is requested herewith, and authorization is made to debit our deposit account for the applicable fee for a large entity. It is noted that April 13, 2008 fell on a Sunday. Thus, the filing of this Response on Monday, April 14, 2008 is timely with a one-month extension of time.

If any additional fees are due, such fees may be charged to our firm's Deposit Account No. 50-1039.

The Examiner is invited to call the undersigned to further discuss any of these matters.

Respectfully submitted,

Date: April 14, 2008



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